

REMARKS

Claims 33-38 are pending in this application. By this Amendment, claims 33 and 35 are amended and claims 25-32 are canceled. Support for the amendments to the claims may be found, for example, in the specification at paragraph [0005]. No new matter is added.

Entry of the amendments is proper under 37 CFR §1.116 because the amendments: (a) place the application in condition for allowance for the reasons discussed herein; (b) do not raise any new issue requiring further search and/or consideration as the amendments amplify issues previously discussed throughout prosecution; and (c) place the application in better form for appeal, should an appeal be necessary. The amendments are necessary and were not earlier presented because they are made in response to arguments raised in the final rejection. Entry of the amendments is thus respectfully requested.

In view of the foregoing amendments and following remarks, reconsideration and allowance are respectfully requested.

I. Telephone Interview

The courtesies extended to Applicants' representative by Examiner Aulakh during the telephone interview held February 13, are appreciated. The reasons presented during the interview as warranting favorable action are incorporated into the Remarks below, which constitute Applicants' record of the interview.

II. Enablement Rejection under 35 U.S.C. §112, First Paragraph

The Office Action rejects claims 33-38 under the enablement requirement of 35 U.S.C. §112, first paragraph. By this Amendment, claims 33 and 35 are amended in light of the Examiner's helpful suggestions discussed during the telephone interview.

As discussed during the telephone interview, the references cited in the July 29, 2008 Amendment support independent method claims 33-35. Specifically, Sugano and Baylis provide support for amended claim 33, which recites "treating renal injury;" Imagawa

provides support for claim 34, which recites "treating hyperaldosteronism;" and Dogrul provides support for amended claim 35, which recites "treating neuropathic pain." Support for the amendment to claim 33 may be found in the specification at paragraph [0005], wherein the specification refers to Baylis (Non-patent Document 6). Baylis, a paper that describes T-type calcium channel participates in occurrence of renal injury, is provided as an example of what the specification and claims referred to as renal disorder. Similarly, support for the amendment to claim 35 may be found in the specification at paragraph [0005], wherein the specification refers to McCallum (Non-patent Document 9). McCallum, a paper that describes T-type calcium channel participates in occurrence of neuropathic pain, is provided as an example of what the specification and claims referred to as neurogenic pain. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

III. Rejection under 35 U.S.C. §112, Second Paragraph

The Office Action rejects claims 33-38 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully traverse the rejection.

The Office Action asserts that the term "compound comprising a T-type calcium channel blocker" is indefinite and queries whether this compound is different from formula (1). This compound is specifically defined by the further language found in each of claims 33-35, which recite: "T-type calcium channel blocker is an optically active 1,4-dihydropyridine compound or a pharmaceutically acceptable salt thereof, of formula (1)." Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

IV. Rejection Under 35 U.S.C. §103

The Office Action rejects claims 25-38 under 35 U.S.C. §103(a) over Masumiya, Haruko et al., Effects of Ca²⁺ channel antagonists on sinus node: Prolongation of late phase 4 depolarization by efonidipine," 335 European Journal of Pharmacology 15-21 (1997)

("Masumiya") in view of U.S. Patent No. 4,535,073 to Kimura et al. ("Kimura"). By this Amendment, claims 25-32 are canceled, rendering their rejection moot. As to the remaining claims, Applicants respectfully traverse the rejection.

The Office Action asserts that the obviousness rejection of claims 25-38 is maintained for the reasons of record. However, it appears that method claims 33-38 have not been fully considered. The previous Office Action addressed canceled claims 1-24. These claims were either composition or therapeutic/preventative agent claims. Thus, the Office Action has not established a prima facie case of obviousness with respect to method claims 33-38, which were newly added with the July 29, 2008 Amendment. The Patent Office has a burden of clearly and explicitly articulating the reason(s) why the claimed invention would have been obvious. *See* MPEP 2142. Therefore, the Patent Office's burden has not been met. Moreover, the combination of Masumiya and Kimura would not have rendered obvious the methods of claims 33-38 because they do not teach or suggest the various steps and features of these methods.

Claims 33-35 would not have been rendered obvious by Masumiya and Kimura. Claims 36-38 respectively depend from claims 33-35 and, thus, also would not have been rendered obvious by Masumiya and Kimura. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

V. Conclusion

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of the application are earnestly solicited.

Although Applicants assert that the claims are in condition for allowance, Applicants respectfully request that because the method claims have not been substantively addressed in the Final Rejection, that if the claims are not found to be currently allowable, a new Office

Action be issued to allow Applicants an opportunity to respond to any rejection of the method claims.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,



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